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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,997	12/24/2003	Yukio Nihei	245553US0CONT	9427

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

NOTIFICATION DATE	DELIVERY MODE
09/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/743,997	NIHEI ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11-15,30,32,35-42 and 44-48* is/are pending in the application.

4a) Of the above claim(s) *16-19 and 22-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11-15,30,32,35-42 and 44-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed **6/13/07** presents remarks and arguments to the office action mailed **3/13/07**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Search was performed for all anti-inflammatory active substance

Status of Claims

Claims 1, 11-15, 30, 32, 35-42, and 44-48 are examined.

Claims 2-4, 6-10, 20-21, 27-29, 31, 43 and 49 are cancelled.

Claims 16-19 and 22-26 are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,11-15, 30, 32, 35-42, and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nihei et al. Jpn. J. Cancer Res. 90, 1016-1025, Sept.,1999, taken with Hori et al. ,Med. Sci Monit, in view of Fex et al., US 3,732,260 and Sugawara et al., US 6,458,347.

Nihei et al. teach the combination of dexamethasone (an anti inflammatory agent) with AC 7700 ((Z)-N-[2-methoxy-5[2(3,4,5-trimethoxyphenyl)vinyl]phenyl]-L-serinamide), a tubulin polymerization-inhibitory active substance (see page 1023, lft col. last five lines) as required by instant claims 1, 30, 32 and 35. Please note that MPEP 2112.01 states "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Nihei et al. teach treating human

carcinogens. Nihei do not however, teach the use of the compounds as one anti-tumor agent, but rather separately.

Hori et al. teach AC 7700,((Z)-N-[2-methoxy-5[2(3,4,5-trimethoxyphenyl)vinyl]phenyl]-L-serinamide), (see abstract) as an anti –cancer agent, with anti-cancer activity as required by instant claims 1 and 30, wherein the unit dosage of the AC 7700 is 10 mg/kg in a unit dosage (see page 28 highlighted), as required by instant claims 14, 37, 41 and 47. 10 mg/kg is within the claim limitation, for example, if the weight of the patient is 50 kg, then the unit dose is 500 mg. Please note that AC 7700 is combrestatin-4, thus making claims 39 and 44 obvious variations.

Fex et al. teach administration of steroidal compounds with other pharmaceutically active agents (see col. 4 lines 33+) as in claim 1, wherein the unit dose of the steroid is 10-100 mg (see col. lines 33-61) as required by instant claims 15, 38 42 and 48. Also Fex teaches the compounds (steroids) can be used in treatment with any anti-cancer agent (see col. 2 lines 15+) simultaneously or sequentially. Adjuvant therapies may be administered either together as a combination, separately, or sequentially. This is a well known fact in the art of adjuvant therapy, and one of ordinary skill in the art would have known how to administer the drugs.

Sugawara et al teach a complex drug formulation comprising ~~the~~ anticancer cancer drug taxane and betamethasone (see col. 4, lines 50-67). In view of this disclosure, one of ordinary skill in the art would have been motivated to combine the teachings to Fex et al. with that of Sugawara et al, substitute the taxane drug disclosed

by Sugawara et al to AC-7700 and combine with a steroid to form a single agent for the treatment of cancer.

Although Hori et al. do not teach using the different drugs in one combination therapy, one skilled in the art would have being motivated to combine the teachings of Hori et al. with that of Nihei to arrive at the instant subject matter. Since Nihei et al. teach the combination of both drugs, one of ordinary skill in the art would have been motivated to make and use the claimed invention at the time the invention was made. Nothing unobvious is seen in doing so.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. *See Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964).

The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Also as stated in the MPEP, the rationale for combining references is a recognition, expressly or impliedly in the prior art, or drawn from a convincing line of

reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). Since these agents are known for there specific functions, integrating them would not differ, as each will be considered to function independently. The properties will still be the same whether separately or combined in one.

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

Response to Argument

Applicant argues that the term "combined" on page 1023 of Nihei et al. was given its broadest reasonable interpretation; [illegible] that the drugs are not present in a single composition; and that Nihei et al. relate to sequential administration.

Applicant's arguments have been carefully considered, but found unpersuasive. Instant claim 36 and 45 recite either administering separately, simultaneously or sequentially, which is met by the Nihei et al. reference. As stated above, the rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
8/27/07

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER